NCL 100 YEARS CONSUMER ADVOCACY National Consumers LEAGUE

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NATIONAL CONSUMERS LEAGUE

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Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 00N-1351 "Fresh" Claims

The National Consumers League and Consumer Federation of America appreciate this opportunity to comment on whether use of the term "fresh" in labeling of foods processed with alternative technologies is truthful and not misleading and what criteria the Food and Drug Administration (FDA) should apply when considering use of the term with alternative technologies.

NCL and CFA have a long history of exposing consumer frauds, including misbranding of food products. Since the late 1980s, we have taken a particular interest in "fresh" label claims that are false or misleading.

At the outset, we would like to reiterate our support of the July 13, 2000 letter from the Safe Food Coalition calling for mandatory heat pasteurization of all juice until alternative technologies are proven to be as effective. The term "pasteurization" has become synonymous with "safety" in the consumer's mind due to its widespread use on milk and juice cartons. The vast majority of consumers do not differentiate between heat treatment and alternative treatments. The key issue is effective pathogen destruction by any approved means.

NCL and CFA strongly support the current regulation governing use of the term "fresh" in food labeling and vigorous enforcement of that rule by FDA. FDA issued the current regulation, 21 C.F.R. § 101.95, in 1993 because of persistent misuse of the term "fresh" and resulting consumer confusion. 58 Fed. Reg. 2302, 2401 (Jan. 6, 1993). The principal abuse, which the rule was intended to prevent, was use of the term "fresh" to "imply that a product is unprocessed, when in fact it has been processed." 58 Fed. Reg. at 2402. The regulation provides that the term "fresh," when used in a manner that suggests or implies that the food is unprocessed, means that the food is "in its raw state and has not been frozen or subjected to any form of thermal processing or any other form of preservation." 21 C.F.R. § 101.95(a). Exceptions are made for approved waxes and coatings, post-harvest use of approved pesticides, application of a mild chlorine or mild acid wash on produce, and irradiation up to a maximum dose of 1 kiloGray.

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We believe that the "fresh" regulation is as necessary today as it was in 1993 when it was promulgated. Certain food manufacturers continue to use label claims to falsely imply that processed products are unprocessed or to blur the distinction between "not from concentrate" and "from concentrate" products. Some recent examples of processed foods that have made "fresh" claims in violation of the FDA regulation include a pasteurized reconstituted apple juice; a line of canned vegetables carrying the brand name "Fresh Cut"; a thermally processed salsa containing preservatives; and a line of thermally processed tomato products identified as Old California™ "Fresh from the Field." Other products falsely imply they are unprocessed without actually using the word "fresh" (e.g., Minute Maid® pasteurized, from concentrate orange juice claims it is "100% pure squeezed"). It is clear from these examples that FDA must continue to police use of "fresh" and related claims on processed foods.

In the preamble to the final "fresh" rule, FDA stated that the criterion for determining whether "fresh" may appropriately be used to describe foods treated with alternative technologies is "the effect that the process has on a food." 58 Fed. Reg. at 2404. Specifically, FDA stated that the agency would consider whether the technology produced "meaningful differences" in the appearance, nutrient content, and physical and sensory qualities of the raw food. 58 Fed. Reg. at 2404. NCL and CFA believe that these factors are the ones most consumers would also consider relevant in judging whether or not a food is "fresh." Therefore, only if a technology has no significant effect on the appearance, nutrient content, and organoleptic qualities (e.g., taste and texture) of the food would it be appropriate to permit a food treated with that technology to be labeled "fresh." This is the rationale for permitting "fresh" claims for foods that have been refrigerated.

Applying these criteria to the alternative technologies discussed in the report "Kinetics of Microbial Inactivation for Alternative Food Processing Technologies," it appears that most would not qualify for "fresh" claims. Some of these technologies (e.g., microwave and radio frequency; ohmic and inductive heating) involve thermal processing; others (e.g., high pressure processing, high voltage arc discharge) alter the structure and appearance of the treated food, while others (e.g., pulsed light, pulsed X-rays) have not been adequately researched. FDA should consider carefully whether any of these alternative technologies qualify for a "fresh" claim under the criteria listed above. For some of these technologies, we do not have sufficient information at this time to offer an opinion. However, we believe that all forms of pathogen destruction should be considered the same for purposes of "fresh" claims unless and until the processor can show there is a meaningful difference.

Where a technology does have a significant effect on the appearance, nutrient content, or organoleptic properties of a food, an unqualified "fresh" claim is inappropriate. However, it may be appropriate, on a case-by-case basis, to allow qualified "fresh" claims for products treated

with such technologies.[1] For example, FDA may wish to consider allowing qualified "fresh" claims for processed fruit and vegetable juices. FDA's proposed juice HACCP rule would require a 5-log reduction in the most resistant pathogens of public health significance for all fruit and vegetable juices, thus effectively making pasteurization mandatory for all juices. If finalized, this would make juice, like milk, a product recognized by consumers as nearly always pasteurized or otherwise processed. In that event, use of the term "fresh" on juice labels would have to be qualified. FDA may then consider permitting qualified "fresh" claims that identify the processing technology used (e.g., "squeezed fresh, then pasteurized for safety"); "fresh squeezed - pasteurized," "fresh squeezed - irradiated, for safety," "fresh pressed - processed with ultraviolet light"). Such claims should not be permitted for product made from concentrate[2].

NCL and CFA are grateful for this opportunity to share our views on an important consumer protection regulation.

Respectfully submitted,

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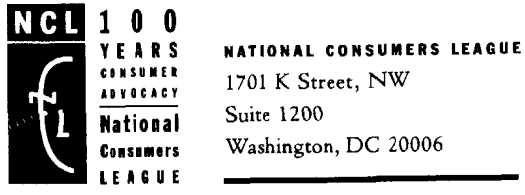
[1] NCL supports FDA's current regulation that permits "packed from fresh _____" to differentiate products made directly from fresh ingredients versus those made from concentrated or dehydrated ingredients.

[2] For most food products, the fact that a product is reconstituted must be indicated on the label with the words "reconstituted" or "from concentrate." See, e.g., 21 C.F.R. § 146.145(c); 146.185(a)(2). This is not true for tomato concentrates which generally must be labeled as "tomato puree," "tomato pulp," or "tomato paste." 21 C.F.R. § 155.191(a)(3). NCL believes that all reconstituted products should be required to bear labeling indicating this fact so that consumers can distinguish between "from concentrate" and not from concentrate" products.



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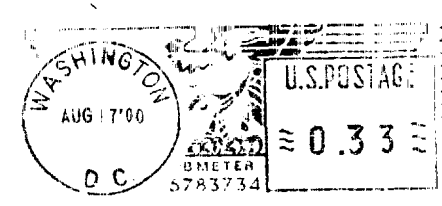

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